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Effectiveness of the fetal pillow to prevent adverse maternal and fetal outcomes at full dilatation cesarean section in routine practice

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Conflicts of interest

None

ABSTRACT

Introduction: The fetal pillow has been suggested to reduce maternal trauma and fetal adverse outcomes when used to disimpact the fetal head at full dilatation cesarean section. **Material and methods:** We performed a retrospective cohort study of the use of the fetal pillow device at full dilatation cesarean section between September 2014 and March 2018 at Liverpool Women's Hospital, a large UK teaching hospital. **Results**: There were 471 cases of full dilatation cesarean section during the study period and 391 were included for the analysis; 170 used the fetal pillow and 221 cases were delivered without. We did not demonstrate any benefit in the significant maternal outcomes of; estimated blood loss >1000ml or >1500ml, need for blood transfusion or duration of hospital stay, from the use of the fetal pillow. We did not demonstrate any improvement in fetal outcome following use of the fetal pillow; arterial pH <7.1, apgar score <7 at 5 mins or admission to the neonatal unit. For deliveries undertaken at or below the level of the ischial spines there was likewise no benefit from fetal pillow use except in a reduced risk of an arterial pH <7.1 (0.39 (0.20 - 0.80), 0.0094) however admission to the neonatal unit was unaffected. **Conclusions:** This is the largest study to date on the use of the fetal pillow at full dilatation cesarean section. We did not demonstrate any statistically significant benefit from the use of the fetal pillow to prevent any of maternal or fetal adverse outcomes at full dilatation cesarean section in routine clinical use. Further randomised studies are required to prove clinical benefit from this device prior to more widespread use.

Keywords

fetal pillow, cesarean section, fetal head, obstetrics, fetal adverse outcomes

Abbreviations:

FDCS full dilatation cesarean section

Key Message:

The use of the fetal pillow at full dilatation cesarean section appears to be ineffective at reducing significant maternal or fetal complications.

INTRODUCTION

Cesarean section at full cervical dilatation (FDCS) occurs in 1.24-2.1% of all deliveries (1, 2) and is associated with both maternal and fetal complications, including maternal trauma and low cord pH (3). With the rate of cesarean section continuing to rise and some concerns raised about reducing skills in complex instrumental delivery, it is likely that this trend will continue.

The fetal pillow is a one-use disposable silicone device consisting of a soft flat base with a balloon compartment, which can be inserted into the vagina and then inflated in order to elevate the fetal head prior to FDCS (Safe Obstetric Systems, Essex, UK). The use of the fetal pillow has been suggested to reduce maternal trauma from bleeding and uterine or vaginal tears at FDCS (4). However, a recent meta-analysis of the limited data available suggests that reverse breech extraction for delivery of the fetus at FDCS is superior to vaginal push methods. The authors of this review were unable to formally assess the use of fetal pillow due to a lack of evidence (5).

Use of the fetal pilow has been suggested to reduce blood loss, improve cord pH and reduce duration of hospital admission when compared to no manipulation or elevation of the fetal head manually by an assistant with their hand within the vagina (6, 7). A recent study also suggested that fetal pillow usage reduced hospital stay by 9 hours (8). A subsequent randomised controlled trial did suggest that use of the fetal pillow at FDCS reduced the incidence of uterine extensions but no other outcome (4).

This study was designed to review whether use of the fetal pillow at FDCS reduced estimated blood loss and need for transfusion when compared to cases where a fetal pillow had not been used.

MATERIAL AND METHODS

We performed a retrospective cohort study of all cases where a cesarean section for a singleton pregnancy was performed at full dilatation between September 2014 and March 2018 at Liverpool Women's Hospital, a large UK teaching hospital. Each case was categorised by whether a fetal pillow was or was not used. All outcomes were obtained from the hospital electronic patient record systems Meditech and neonatal outcomes from Badger.net.

The fetal pillow was introduced at Liverpool Women's Hospital as an option for the management of FDCS in September 2014. All senior trainees and consultants were fully trained in the use of the fetal pillow, FDCS and rotational vaginal deliveries. The decision to use a fetal pillow or not was left to the individual clinician.

Statistical analysis was performed using a t-test for normally distributed values and relative risk when comparing between interventions.

Ethical approval

Ethical approval was provided as part of hospital audit processes on 2 June 2015 (Liverpool Women's Hospital 2016/016).

RESULTS

There were 471 cases of FDCS during the study period. We excluded 70 cases; 48 twin pregnancies, 18 breech presentation, 13 had been misreported as being at full dilatation and a single antepartum stillbirth. This left 391 cases for assessment of which 170 had used a fetal pillow and 221 where a fetal pillow had not been used.

There were no significant differences between the groups in maternal age, BMI, ethnicity, onset of labour or fetal position. There were statistical differences in station with fewer fetal pillow cases reported as above (relative risk: 0.37 (95% confidence interval: 0.25 – 0.57); $p<0.0001$) and more below the ischial spines (2.34 (1.68 – 3.26); <0.0001). There were more nulliparous women managed with fetal pillow (1.19 (1.08 – 1.31); 0.0009) (Table 1).

Maternal outcomes such as estimated blood loss; haemorrhage >1000ml (1.24 (0.84-1.83); 0.29) or >1500ml (1.39 (0.69-2.81); 0.35), uterine extensions (as defined by the attending clinician) and

need for blood transfusion (1.16 (0.46-2.90; 0.76) were not influenced by the use of the fetal pillow. Likewise time to discharge was unaffected by fetal pillow usage (Table 2).

All neonates were born alive during the study period irrespective of fetal pillow usage. There was no statistical difference in neonatal outcomes by use of fetal pillow for apgar score <7 at 5 minutes (1.30 (0.60 - 2.82); 0.51) and admission to the neonatal unit (0.72 (0.40-1.31); 0.29) (Table 3). There was no statistically significant effect on arterial pH <7.1 in those neonates managed with fetal pillow compared to those without fetal pillow (0.54 (0.28-1.02; 0.06)). There were no episodes of fetal skull fracture or other birth trauma in the study period.

We further assessed those deliveries potentially thought to be most likely to benefit from the use of the fetal pillow, namely those at or below the level of the ischial spines (fetal pillow used 139, no fetal pillow 126) (Table 4) or below the ischial spines (fetal pillow used 72, no fetal pillow 40 (Table 5). There was no benefit from the use of the fetal pillow on maternal outcomes of; estimated blood loss >1000ml either at the spines or below (1.61 (0.95 - 2.72), 0.0747) or below the spines (2.78 (0.64 - 12.06), 0.1726). There was no reduction in estimated blood loss >1500ml either at the spines (2.72 (0.90 - 8.22), 0.0761) or below the spines (2.22 (0.26 - 19.21), 0.726). There was no effect upon the need for maternal blood transfusion either at the spines (1.81 (0.56 - 5.88), 0.3213) or below the spines (2.22 (0.26 - 19.21), 0.726). There was no effect on the frequency of uterine extensions when the fetal head was at the spines or below (0.87 (0.56 – 1.36), 0.56) or when it was below the spines (0.90 (0.41 – 1.99), 0.80).

Fetal outcomes from use of the fetal pillow at or below the ischial spines showed no effect on apgar score <7 at 5 minutes (1.30 (0.51 - 3.30), 0.5881), or admission to the neonatal unit (0.67 (0.31 - 1.39), 0.2793), but did reduce the chance of the neonate being born with an arterial pH <7.1 (0.39 (0.20 - 0.80), 0.0094). There was no benefit in outcome from fetal pillow usage when station was below the spines for apgar score <7 at 5 minutes (3.33 (0.42 – 26.72), 1.134), neonatal admission (0.78 (0.26 - 2.29), 0.6485) or arterial pH <7.1 (0.56 (0.23 - 1.37), 0.2008).

DISCUSSION

The management of the fetus that does not deliver vaginally after full dilatation represents a common and complex intrapartum issue. Changes in clinician skills may have led to an increased

use of FDCS with its associated morbidity rather than more complex vaginal deliveries (9). It is therefore attractive to look to devices such as the fetal pillow to improve clinical outcomes in these cases.

Our study represents the largest study to date on the routine clinical use of the fetal pillow to assist delivery of the fetus at FDCS.We were not able to demonstrate any clinically relevant benefit from the use of the fetal pillow over normal methods either in maternal outcomes such as haemorrhage or in fetal outcomes. There was no benefit when the presenting part was at the level of the ischial spines or lower, suggesting a more deeply impacted fetal head. The only factor reaching statistical significance was a reduction in low arterial pH with fetal pillow use but without a concomitant reduction in admission to the neonatal unit it is unclear what if any clinical relevance there is from this. Our findings are consistent with those of Hanley et al. but we were not able to identify a meaningful difference in length of hospital stay.

The limitations of our study include its non-randomised, retrospective nature and as such there may be some unknown factors about patient selection. It is perfectly plausible that patient selection on who received the fetal pillow on had an influence on these findings as demonstrated by the increased usage of the fetal pillow when station was below the Ischial Spines. Likewise, we did not assess clinician experience although due to the size and duration of the study the authors feel this is unlikely to have been a major influencing factor. However, this study is large and does reflect the experience of routine clinical use of the fetal pillow within a large UK maternity unit where usage of the fetal pillow was well established. There were more nulliparous women in the fetal pillow group than in those managed without and this may have been an influencing factor on the decision to use the fetal pillow, although it is unclear what effect this would have had on the main outcome measures of haemorrhage and neonatal adverse outcome. Further limitations of this study include a higher number of deliveries for fetal distress in the non-fetal pillow group, which may have influenced the decision not to use the fetal pillow, although as there was no difference in apgar score or neonatal intensive care unit admission it is unlikely to reflect true fetal compromise.

The only randomised study of fetal pillow use demonstrated a significant difference in blood loss >1000ml, need for blood transfusion and in surgeon grading of major uterine extension at cesarean section (4). We observed no effect on uterine extensions between those women managed with a fetal pillow and those without in any subgroup.

CONCLUSION

We demonstrate the largest study of use of the fetal pillow at FDCS. Our data did not demonstrate any significant clinical improvement in maternal outcomes related to clinically important features of blood loss, transfusion, uterine extensions or hospital stay. The only improvement in neonatal outcome with the use of the fetal pillow was less cases of arterial pH <7.10 where the pillow was used at or below the ischial spines, but without a concomitant effect on apgar score or neonatal unit admission making interpretation of the value of this finding difficult. Furthermore, when looking at the use of the fetal pillow in cases of a presumed deeply impacted head below the ischial spines even this positive finding was no longer present, although in these subgroups the data is limited and confidence intervals are wide.

We suggest that clinician preference should guide the use of fetal pillow at FDCS, further guided by local considerations of healthcare costs and service demands. Only when sufficient effectiveness and safety data is available would routine use be justified.

References

1. Murphy DJ, Liebling RE, Verity L, Swingler R, Patel R. Early maternal and neonatal morbidity associated with operative delivery in second stage of labour: a cohort study. Lancet. 2001;358:1203-7.

2. Corry EMA, Ramphul M, Rowan AM, Segurado R, Mahony RM, Keane DP. Exploring full cervical dilatation caesarean sections-A retrospective cohort study. Eur J Obstet Gynecol Reprod Biol. 2018;224:188-91.

3. Hager RM, Daltveit AK, Hofoss D, et al. Complications of cesarean deliveries: rates and risk factors. Am J Obstet Gynecol. 2004;190:428-34.

4. Seal SL, Dey A, Barman SC, Kamilya G, Mukherji J, Onwude JL. Randomized controlled trial of elevation of the fetal head with a fetal pillow during cesarean delivery at full cervical dilatation. Int J Gynaecol Obstet. 2016;133:178-82.

5. Jeve YB, Navti OB, Konje JC. Comparison of techniques used to deliver a deeply impacted fetal head at full dilation: a systematic review and meta-analysis. BJOG. 2016;123:337-45.
6. Seal SL, Dey A, Barman SC, Kamilya G, Mukherji J. Does elevating the fetal head prior to delivery using a fetal pillow reduce maternal and fetal complications in a full dilatation caesarean section? A prospective study with historical controls. J Obstet Gynaecol. 2014;34:241-4.
7. Safa H, Beckmann M. Comparison of maternal and neonatal outcomes from full-dilatation cesarean deliveries using the Fetal Pillow or hand-push method. Int J Gynaecol Obstet. 2016;135:281-4.
8. Hanley I, Sivanesan K, Veerasingham M, Vasudevan J. Comparison of outcomes at full-dilation cesarean section with and without the use of a fetal pillow device. Int J Gynaecol Obstet. 2020;150:228-233.
9. Tempest N, Hart A, Walkinshaw S, Hapangama DK. A re-evaluation of the role of rotational forceps: retrospective comparison of maternal and perinatal outcomes following different methods of birth for malposition in the second stage of labour. BJOG. 2013;120:1277-84.

Legends

Figure 1. Selection of cases for assessment. FDCS, full dilatation cesarean section; LWH, Liverpool Women's Hospital.

Table 1: Population characteristics by use of fetal pillow.

Table 2: Maternal outcomes by use of fetal pillow.

Table 3: Fetal and neonatal outcomes by use of fetal pillow.

Table 4: Maternal and fetal outcomes for deliveries at the ischial spines or lower.

Table 5: Maternal and fetal outcomes for deliveries below the ischial spines.

	Fetal Pillow (n= 170) n (%)	**No Fetal Pillow (n=221) n (%)**	**P value or RR**
Age (years; median, quartiles)	30 (27 – 33)	30 (27 – 34)	P = 0.43
BMI (kg/m^2; median, quartiles)	25.7 (22.9 – 28.5)	25.7 (23.1 – 29.5)	P = 0.31
Ethnicity:			
Caucasian	145 (85.3)	195 (88.2)	
Black	7 (4.1)	3 (1.4)	
Asian	8 (4.7)	6 (2.7)	
Chinese	2 (1.2)	3 (1.4)	
Other/Not stated	8 (4.7)	14 (6.3)	
Nulliparous	148 (87.1)	161 (72.9)	1.19 (1.08 – 1.31); 0.0009
Onset of labour:			
Induced	87 (51.1)	116 (52.5)	0.98 (0.80 – 1.18); 0.7972
Position:			
OA	34 (20.0)	36 (16.3)	1.23 (0.80 – 1.88); 0.3428
OP	72 (42.4)	96 (43.4)	0.98 (0.77 – 1.23); 0.8300
OT	60 (35.3)	74 (33.5)	1.05 (0.80 – 1.39); 0.7081
Not stated	4 (2.4)	15 (6.8)	0.35 (0.12 – 1.03); 0.0556

Station:			
Above spines	23 (13.5)	80 (36.2)	0.37 (0.25 – 0.57); <0.0001
At spines	67 (39.4)	86 (38.9)	1.01 (0.79 – 1.30); 0.9203
Below spines	72 (42.4)	40 (18.1)	2.34 (1.68 – 3.26); <0.0001
Not stated	8 (4.7)	15 (6.7)	0.69 (0.30 – 1.60); 0.3897
Indication for CS:			
Failed instrumental	63 (37.1)	43 (19.4)	1.90 (1.36 – 2.66); <0.0001
Fetal distress	14 (8.2)	49 (22.2)	0.37 (0.21 – 0.65); 0.0005
Delay in labour	90 (52.9)	120 (54.3)	1.06 (0.88 – 1.29); 0.5274
Maternal reason	3 (1.8)	7 (3.2)	0.31 (0.08 – 1.16); 0.0807
Not stated	0	2 (0.9)	0.14 (0.01 – 2.98); 0.2102

Table One: Population characteristics by use of fetal pillow

	Fetal Pillow (n= 170)	**No Fetal Pillow (n=221)**	**Relative Risk (95% CI)**
Estimated blood loss (ml; median, quartiles)	600 (500 – 900)	600 (500 – 800)	
Estimated blood loss >1000ml n (%)	39 (22.9)	41 (18.6)	1.24 (0.84 - 1.83); 0.29
Estimated blood loss >1500ml n (%)	15 (8.8)	14 (6.3)	1.39 (0.69 - 2.81); 0.35
Blood transfusions n (%)	8 (5.4)	9 (4.1)	1.16 (0.46 - 2.9); 0.76
Uterine Extension	37 (21.8)	47 (21.3)	1.02 (0.70 – 1.50); 0.91
Delivery to discharge (days; median, quartiles)	2 (2 – 3)	2 (2 – 3)	

Table 2: Maternal outcomes by use of fetal pillow

Table 3: Fetal and neonatal outcomes by use of fetal pillow

	Fetal Pillow (n= 170)	**No Fetal Pillow (n=221)**	**Relative Risk (95% CI); *p***
Birthweight (grams; median, Quartile)	3658 (3350 - 3958)	3650 (3328 - 4030)	
Apgar <7 at 5 mins n (%)	12 (7.1)	12 (5.4)	1.30 (0.60 - 2.82); 0.51
Arterial pH <7.1 n (%)	12 (7.1)	29 (13.1)	0.54 (0.28 - 1.02); 0.06
NICU admission n (%)	15 (8.8)	27 (12.2)	0.72 (0.40 - 1.31); 0.29

NICU, neonatal intensive care unit.

	Fetal Pillow (n= 139)	**No Fetal Pillow (n=126)**	**Relative Risk**
Estimated blood loss (ml; median, quartiles)	600 (500 – 887.5)	600 (500 – 800)	
Estimated blood loss >1000ml n (%)	32 (23.0)	18 (14.2)	1.61 (0.95 - 2.72), 0.07
Estimated blood loss >1500ml n (%)	12 (8.6)	4 (3.2)	2.72 (0.90 - 8.22), 0.08
Blood transfusion n (%)	8 (5.6)	4 (3.2)	1.81 (0.56 - 5.88), 0.32
Uterine Extension	30 (21.6)	31 (24.6)	0.87 (0.56 – 1.36), 0.56
Apgar <7 at 5 mins	10 (7.2)	7 (5.6)	1.30 (0.51 - 3.30), 0.59
Arterial pH <7.1 n (%)	10 (7.2)	23 (18.3)	0.39 (0.20 - 0.80), 0.001

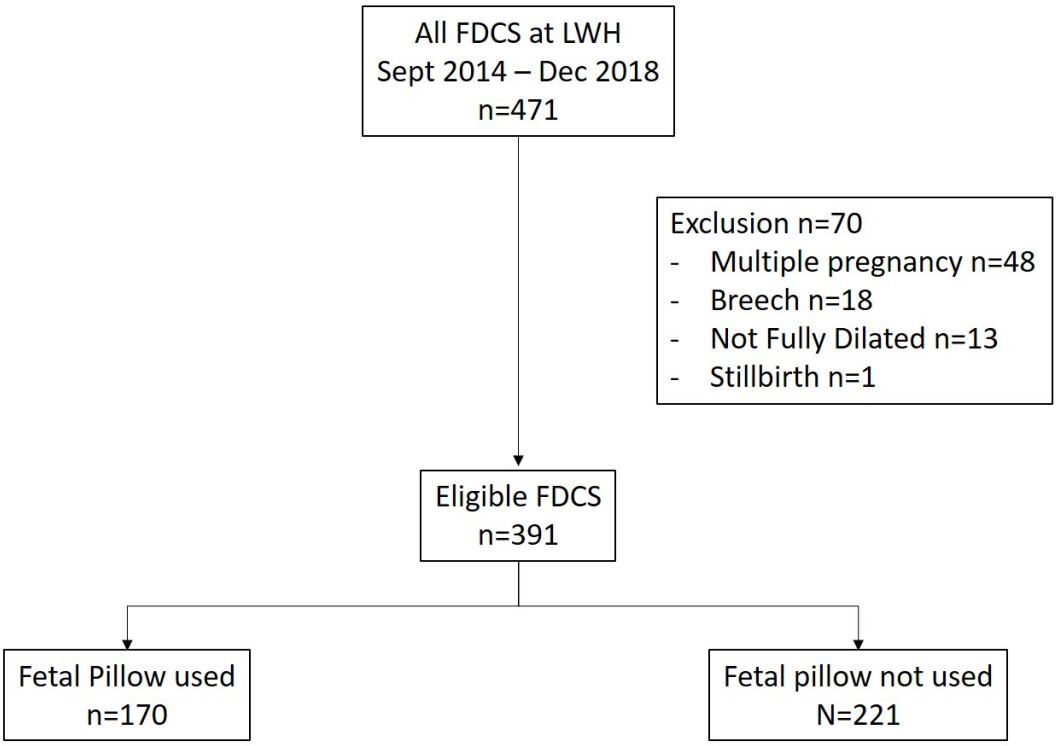
Neonatal unit admission	11 (7.9)	15 (11.9)	0.67 (0.31 - 1.39), 0.28

Table 4: Maternal and fetal outcomes for deliveries at the ischial spines or lower

	Fetal Pillow (n= 72)	**No Fetal Pillow (n=40)**	**Relative Risk (95% CI); *p***
Estimated blood loss (ml; median, quartiles)	600 (500 – 900)	600 (500 – 800)	
Estimated blood loss >1000ml n (%)	10 (13.9)	2 (5.0)	2.78 (0.64 - 12.06); 0.17
Estimated blood loss >1500ml n (%)	4 (5.6)	1 (2.5)	2.22 (0.26 - 19.21); 0.73
Blood transfusion n (%)	4 (5.6)	1 (2.5)	2.22 (0.26 - 19.21); 0.73
Uterine Extension	13 (18.1)	8 (20.0)	0.90 (0.41 – 1.99); 0.80
Apgar <7 at 5 mins	6 (8.3)	1 (2.5)	3.33 (0.42 – 26.72); 1.13
Arterial pH <7.1 n (%)	8 (11.1)	8 (20)	0.56 (0.23 - 1.37); 0.20

Neonatal unit admission	7 (9.7)	5 (12.5)	0.78 (0.26 - 2.29); 0.65

Table 5: Maternal and fetal outcomes for deliveries below the ischial spines



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